

Amendment and Response

Applicant: Timothy R. Ryan et al.

Serial No.: 09/982,299

Filed: October 16, 2001

Docket No.: M190.137.101

Title: ANNULOPLASTY BAND AND METHOD

REMARKS

This Response accompanies the concurrently filed RCE application, and is responsive to the Final Office Action mailed September 23, 2003. In that Office Action, claims 1-3, 9-13, 15, 16, 30-33, and 37-41 were rejected under 35 U.S.C. §102(b) as being anticipated by Myers, U.S. Patent No. 5,716,397 ("Myers"). Claims 1-4, 7, 9-13, 15, 16, 30-33, and 37-41 were rejected under 35 U.S.C. §102(b) as being anticipated by Wright et al., U.S. Patent No. 5,306,296 ("Wright"). Claims 5, 6, and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wright in view of Carpentier et al., U.S. Patent No. 5,061,277 ("Carpentier"). Finally, claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Wright or Myers in view of Loch et al., U.S. Patent No. 6,174,332 ("Loch").

With this Response, claims 31 and 32 have been cancelled; claims 1, 10, 16, 20, and 37 have been amended; and claims 42 and 43 added. For at least the reasons provided below, it is believed all pending claims are in a condition for allowance.

Amended claim 1 relates to an annuloplasty band including a sheath and a stiffening element. The stiffening element is entirely disposed within the sheath, and includes first and second eyelet ends. In this regard, a curvature length of the stiffening element is at least one-half the curvature length of the sheath. It is respectfully submitted that none of the cited references teach or suggest at least these limitations.

For example, Myers relates to an annuloplasty device with a removable stiffening element. The only teaching in Myers by which this requisite removable feature is achieved is by at least a portion of the stiffening element extending from the sheath. In particular, each of the embodiments associated with FIG. 3, FIG. 4, and FIGS. 6A-6G specifically requires that the corresponding stiffening element cannot be entirely disposed within the sheath as otherwise set forth in amended claim 1. Nor does Myers suggest such a modification. In fact, Myers teaches away from such a modification as Myers specifically desires both insertion and removal of a stiffener (Myers, column 3, lines 34-46). Were the stiffener to be entirely disposed within the sheath, this necessary insertion and removal feature could not be accomplished.

Wright is similarly unavailing. The relationship of the wire or stiffener 35 relative to the sheath 11 is best described with reference to FIG. 2 of Wright. The sheath 11 forms a ring

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having a shape commensurate with a mitral valve (Wright, column 14, lines 17-22). The view of FIG. 2 illustrates a curvature length of the sheath 11 (e.g., the circumference of the ring shape defined by the sheath 11). The stiffener 35 extends along a minor portion of the sheath's curvature length and clearly has a curvature length that is much less than one-half the curvature length of the sheath 11, as otherwise set forth in amended claim 1. Notably, Wright relies upon this short stiffener length for intended use of the annuloplasty ring 10, whereby drawstrings 20, 21 are tightened (via the external portions 22-25) to reduce a diameter of the ring 10 so as to match a size of the valve being repaired. If the stiffener 35 were any longer than that shown in FIG. 2, this desired feature of Wright would be overtly impeded. Thus, Wright teaches away from the invention of amended claim 1.

In light of the above, it is respectfully submitted that amended claim 1 is not taught or otherwise suggested by the cited references.

Claims 2-9 and 12-16 depend from amended claim 1. As previously described, amended claim 1 is not taught or otherwise suggested by the cited references. Therefore, claims 2-9 and 12-16 are similarly allowable. Additionally, it is noted that amended claim 16 recites that the stiffening element is configured to independently maintain a generally saddle-shape. While it is possible that the stiffening element of Myers or Wright may be flexible enough to be forced to such a shape, the stiffening element of these references cannot, in and of itself, maintain this shape. Therefore, it is respectfully submitted that at least amended claim 16 recites additionally allowable subject matter.

Amended claim 10 relates to an annuloplasty band including a sheath and a stiffening element. The stiffening element is disposed with the sheath and includes first and second end eyelets. Further, the sheath is marked at a first location corresponding to a position of the first end eyelet within the sheath and a second location corresponding to a position of the second end eyelet within the sheath. While Wright and Myers may ambiguously reference a marking on their respective sheaths, neither reference suggests, let alone teaches, the specific marking locations required by amended claim 10. For example, the Examiner has reference column 15, lines 45-49 of Wright as teaching a colored suture. The cited language specifically describes a "colored demarcation suture line 38". As shown in FIG. 2 of Wright, only a single suture line 38

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is provided, and does not correspond to eyelet locations. Instead, the suture line 38 simply indicates a location beyond which implanting sutures must be placed to avoid interference with the internal drawstrings and the stiffener member. Further, there is no suggestion in Wright for a modification of the suture line 38 to mark the first and second eyelet positions, as a surgeon will never need to locate the eyelets during use. Similarly, column 4, lines 16-20 of Myers (referenced by the Examiner) describe providing indicia to delineate a core lumen 36 in the sheet 14. As shown in FIG. 5, the stiffener 28 is not disposed within the core lumen 36, such that any indicia positioned to indicate the core lumen 36 cannot correspond to a position of the stiffener element 28, let alone eyelets formed thereby.

In light of the above, it is respectfully submitted that amended claim 10 is allowable over the cited references. Claim 11 depends from claim 10. For at least the above reasons, then, claim 11 is similarly allowable.

Amended claim 30 relates to an annuloplasty band including a sheath and a stiffening element. The stiffening element is entirely disposed within the sheath. Further, the band has a thickness no greater than 2.5 mm. As previously described, Myers does not teach or suggest an annuloplasty device in which the stiffening element is entirely disposed within an outer sheath. Conversely, as apparently agreed by the Examiner, the vertical thickness of the Wright device is 2.7 mm, in contrast to the limitations of amended claim 30. As such, it is respectfully submitted that amended claim 30 recites allowable subject matter. For at least these same reasons, claim 33, that otherwise depends from amended claim 30, is also allowable over the cited references.

Amended claim 37 relates to an annuloplasty device including a sheath, a reinforcing member, and a visible marking. The reinforcing member forms a first eyelet and is disposed within the sheath such that the first eyelet is located at a first location along a curvature of the sheath. With this in mind, the visible marking is formed on the sheath at this first location. For the reasons previously described with respect to amended claim 10, it is respectfully submitted that none of the cited references teach or otherwise suggest the above limitations. As such, amended claim 37 is allowable over the cited references.

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Claims 38-41 depend from amended claim 37. As previously described, amended claim 37 is not taught or otherwise suggested by the cited references. Therefore, claims 38-41 are similarly allowable.

Newly added claim 42 depends from amended claim 37. As previously described, amended claim 37 is not taught or otherwise suggested by the cited references, such that newly presented claim 42 is similarly allowable. In addition, claim 42 recites that the visible marking is configured to indicate an area within the first eyelet. Support for this limitation is found, for example, in FIGS. 4 and 5. With respect to Wright and Myers, neither reference provides a visible marking that corresponds to an eyelet location, let alone to an area within an eyelet. As such, it is respectfully submitted that claim 42 recites additionally allowable subject matter.

Newly presented claim 43 depends from amended claim 37, and thus for the reasons previously described is allowable over the cited references. In addition, claim 43 recites a second visible marking formed on the sheath at a second location otherwise defined by a location of the second eyelet relative to a curvature of the sheath. None of the cited references teach or otherwise suggest this limitation. Therefore, claim 43 recites additionally allowable subject matter.

CONCLUSION

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 500471.

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The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this response.

Respectfully submitted,

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By their attorneys,

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CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope address to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 23rd day of January, 2004.

By

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